

Notice of Allowability

Application No.

10/057,620

Applicant(s)

SCARIA ET AL.

Examiner

Art Unit

Dave T. Nguyen

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/18/04.
2. ☒ The allowed claim(s) is/are 1-35.
3. ☒ The drawings filed on 11/8/2005 (figures 2 and 3) are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Examiner's Comments

Claim 1 has been amended, and claims 2-35 have been added by the amendment filed November 8, 2004. The examiner acknowledges that both the cover letter and the non-final office action dated May 4, 2004 have a typographical error with respect to claim numbering. Claim 1 should have been typed as pending rather than claim 7. As such, the examiner agrees with applicant that the error is not material to the rejections.

Claims 1-35 are pending. Applicant's amendment to the claims, the sequence listing correction, the newly filed drawing (partial so as to comply with the sequence rules), and the amendment to the specification all obviate all outstanding rejections and objections.

Examiner's Statement of Reasons for Allowance

Currently pending claims together with applicant's response has been considered and is found persuasive with respect to the patentability of the claims. More specifically, Applicant's remarks on page 4 are accurate with respect to the non-anticipation or non-obviousness of the claimed invention, particularly in view of the closest prior art, High WO 01/70763, which claims priority to the provisional application 60/191,331. Instead of mutating the endogenous cleavage site of human Factor VII, High teaches specifically that a furin cleavage site is inserted into the endogenous Factor VII activation site, *e.g.*, between amino acid Arg152-Ile153. As set forth in the remarks, the two concepts and/or teachings are not the same, and thus, do not render one or the other obvious. An insertion of a furin cleavage site is neither the same nor obvious

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variant of a mutation(s) of amino acid residues amino acid Arg152-Ile153. No motivation was provided in the prior art of record so as to modify the teaching of High. In fact, the totality of the prior art of record appear to teach modifying human Factor VII so as to possess an anti-coagulant activity, *e.g.*, see US Pat No. 5824639, US 5739101. The totality of the prior art in general teaches mutation of human factor VII in order to abolish its coagulant activity. As such, the totality of the prior art of record does not teach, suggest, or provide a motivation for one of ordinary skill in the art to arrive at the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Ram Shukla*, may be reached at **571-272-0735**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Dave Nguyen
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Dave', with a long horizontal flourish extending to the right.

DAVE TRONG NGUYEN
PRIMARY EXAMINER